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ATTORNEY DOCKET NUMBER: 0492611-0326 (MIT 8151)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

Applicant: Langer *et al.* Examiner:
Serial No: 09/553,552 Art Unit: 1643
Filed: April, 20, 2000
Title: ENDOSOMOLYTIC AGENTS AND CELL DELIVERY SYSTEMS

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

1. Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98
2. Information Disclosure Statement (Form PTO-1449)
3. Cited Art
4. Return Postcard

Please charge any fees or credit any overpayments to our Deposit Account No. 03-1721.

Respectfully submitted,

C. Hunter Baker, M.D., Ph.D.

Reg. No.: 46,533

CHOATE, HALL & STEWART

Exchange Place

53 State Street

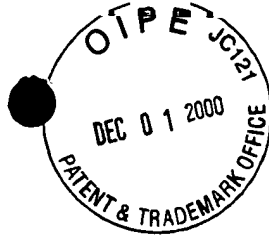
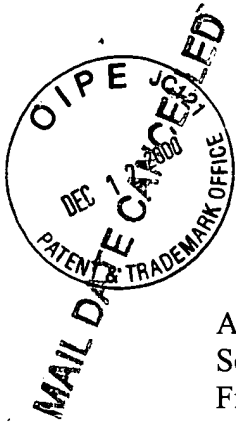
Boston, MA 02109

(617) 248-5000

Dated: November 28, 2000

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Commissioner For Patents, Washington, D.C. 20231
on November 28, 2000



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Title: ENDOSOMOLYTIC AGENTS AND CELL DELIVERY SYSTEMS

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

Sir:

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE
UNDER 37 CFR §§1.56, 1.97 AND 1.98

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants respectfully request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

(Select A, B or C below)

- A. ☐ This Information Disclosure Statement has been filed:
(check 1, 2 and/or 3 below)
1. ☐ within three months of the filing date of the above identified U.S. Patent application;
 2. ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application; and/or
 3. ☒ before the mailing date of the first Office Action on the merits in the above-identified application.

No fee or certification is required.

- B. ☐ This Information Disclosure Statement has been filed more than three months after the filing date of the present application and after the mailing date of this first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311.

(check 1 or 2 below)

1. ☐ The fee of \$240 as set forth in 37 C.F.R. §1.17(p) is enclosed; or
2. ☐ Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that
(check a or b below)
 - a. ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application not more than three months prior to the filing of this Statement; or
 - b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.
 - c. ☐ items indicated by an asterisk were identified in a recent review of related files.

- C. ☐ This Information Disclosure Statement has been filed after the mailing date of either a Final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311 and before payment of an Issue Fee.

(check 1, 2, and 3 below)

1. ☐ The Applicant hereby certifies, as specified in 37 C.F.R. §1.97(e), that:
(check a or b below)
 - a. ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent

Office in a counterpart for this application not more than three months prior to the filing of this Statement.

- b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.
2. ☐ A Petition requesting consideration of the Information Disclosure Statement is attached.
3. ☐ The Petition Fee of \$130 as set forth in 37 C.F.R. §1.17(i)(1) is enclosed.

PART II - Information Cited

- A. ☒ The Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.
- B. ☐ The Applicant hereby makes the following additional information of record in the above-identified application:

PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

- A. ☐ The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):
- B. ☐ The following are remarks concerning the other information cited:

PART IV: Remarks

- A. ☒ Copies of references
(check 1 or 2 below)
1. ☒ A copy of each of the references cited on the attached form PTO-1449
(modified) is enclosed;
2. ☐ Copies of certain of the references cited on the attached form PTO-1449
(modified) are not enclosed because each of these references (indicated by
asterisk) was previously cited by or submitted to the Office in a prior
application, which prior application is relied upon for an earlier filing date
under 35 U.S.C. § 120.
- B. ☒ It is respectfully requested that:
(check 1, 2, and 3 below)
1. ☒ The Examiner consider completely the cited information, along with any
other information, in reaching a determination concerning the patentability
of the present claims;
2. ☒ The enclosed form PTO-1449 be signed by the Examiner to evidence that
the cited patent(s) and publication(s) has (have) been fully considered by
the Patent and Trademark Office during the examination of this
application;
3. ☒ The citations for the patent(s) and publication(s) be printed on any patent
which issues from this application.
- C. ☒ By submitting this Information Disclosure Statement, Applicants make no
representation that a search has been performed, of the extent of any search
performed, or that more material information may not exist.

- D. [X] By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).
- E. [X] By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.
- F. [X] Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

An early and favorable action is hereby requested.

Please charge any additional fees or credit any overpayments to our Deposit Account No. 03-1721.

Respectfully submitted,

By: C Hunter Baker
C. Hunter Baker, M.D., Ph.D.
Reg. No.: 46,533

CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, Massachusetts 02109
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Dated: November 28, 2000

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231 on November 28, 2000
Karen E. Leaps